DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

April 16, 2002

VIA FEDERAL EXPRESS – NEXT DAY

Ms. Catherine D. Boettner
President
Cleveland Tubing Inc.
799 Industrial Drive
Cleveland, TN 37320-2698

Warning Letter No. 02-NSV-19

Dear Ms. Boettner:

During an inspection of your establishment on March 20-25, 2002, our investigator determined that your establishment manufactures medical tubing which is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed deviations from 21 CFR Part 820 including a failure to validate the extrusion process, failure to follow manufacturing specifications, inadequate documentation of device failures, no Medical Device Reporting procedures, and no Quality System Regulation training of firm personnel.

The inspection also revealed that your finished product label failed to bear your firm's name and address as required by 21 CFR Part 801.1. We are enclosing a copy of the medical device labeling regulations.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's Quality System. You are responsible for investigating and determining the causes of the violations identified by the FDA.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject device have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not occur

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper
Director, New Orleans District

CED:JEH:man

Enclosures:
21 CFR Part 801
21 CFR Part 820

cc: Thomas P. Nilson
Quality Manager